REMARKS

Claims 24 through 50 are pending is this application. Claims 35-46 have been widthdrawn as directed to a non-elected species and new claim 50 has been added, leaving claims 24-34 and 47-50 for examination. Claim 24 has been amended to recite an endoscope for transoral delivery of the inner and outer catheters and stent. New claim 50 further defines the outer catheter as extending over a majority of the length of the inner catheter. Claim 47 has been amended to correct dependency. Support for these amendments can be found throughout the specification and drawings, including, for example, FIGS. 4, 6(a) through 6(d), and 8(a) and paragraphs 14, 15, 48, 49, and 58, of the published application. No new matter has been added.

§102(e) Rejections

The present '570 Application is generally directed, for example, to methods and devices for draining pseudocysts. Pseudocysts can occur within the abdominal cavity or peritoneal cavity as a result of a build up of tissue, fluid, debris, pancreatic enzymes and/or blood. In one aspect, the '570 Application describes a stent delivery system for implanting a stent within the gastric or abdominal wall to facilitate draining of a pseudocyst. The stent can be a self-expandable stent adapted to drain a gastric pseudocyst when implanted and having a diameter when expanded that is larger than the diameter of an individual endobiliary tube. As described in the '570 application, endobiliary tubes were previously used to drain pseudocysts, but had certain drawbacks including the need to implant multiple endobiliary tubes and the tendency of the tubes to become blocked or partially obstructed.

A. The Gambale Reference

The Examiner rejects claims 24-28, 30, 31, and 33 pursuant to 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,458,092 to Gambale et al. ("Gambale"). In particular, with respect to independent claim 24, the Office Action states that:

> Gambale discloses a stent delivery system comprising: an inner catheter (80) with a first lumen; perforating means (82,84) slidably disposed in the first lumen; an outer catheter (36) adapted for axial movement relative to the inner catheter; a self expandable stent (70) disposed between the inner and outer catheter.

Office Action at p. 3.

Applicants respectfully traverse this rejection because Gambale fails to suggest or disclose an endoscope or the delivery of gastric pseudocysts via a transoral route.

The Gambale reference is directed to angiogenesis implant devices that are implanted into cardiac tissue to foster the growth of blood vessels. The implants expand when implanted and irritate and slightly injure the surrounding tissue to provoke an injury response that results in angiogenesis. The flow of blood from the surrounding tissue into the implant and pooling of the blood in and around the implant leads to thrombosis and fibrin growth. The healing process leads to angiogenesis in the tissue surrounding the implant.

Unlike Gambale, the present '570 Application claims a gastric pseudocyst drainage stent system for delivery via an endoscope having an inner catheter with a first longitudinally extending lumen, perforating means slidably disposed in said first longitudinally extending lumen, and an outer catheter surrounding the inner catheter and adapted for axial movement relative to the inner catheter. In addition, claim 24 requires a self-expandable stent disposed between the inner catheter and outer catheter and an endoscope for transoral delivery.

Gambale fails to disclose such a system and is instead focused on cardiac applications where an endoscope would be unusable. The Gambale device is configured for percutaneous access via a delivery catheter 36 (Gamble, FIGS. 4A through 4B and col. 9, lines 18-30.). Delivery catheter 36 is guided through a blood vessel and into a cardiac chamber. In particular, catheter 36 is advanced over a guidewire or steered into place and push tube 20 and tubular implant 70 are then advanced from the catheter. As illustrated below, the delivery catheter of Gambale constrains tubular implant 70 and defines the outermost layer of the Gambale device.

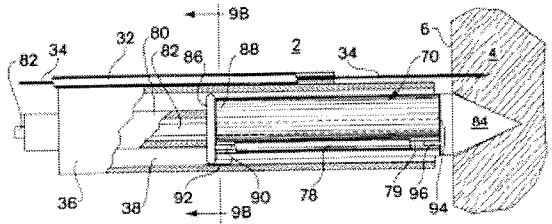

Fig. 9A

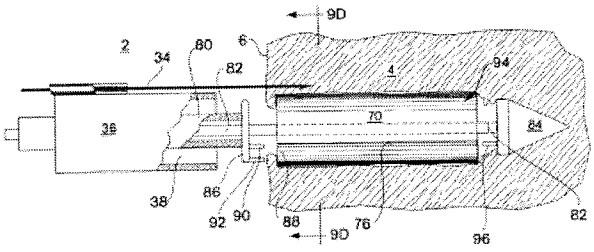

Fig. 9C

Conversely, endoscopes cannot be driven through a blood vessel and into a cardiac chamber as required by Gambable. Endoscopes permit access via a natural body orifice or incision such as transoral approach to the stomach. At a minimum, an endoscope would not fit through a blood vessel. In addition, claim 24 requires an endoscope for housing the inner catheter, outer catheter, and stent. Thus, the system of claim 24 includes an additional outer structure that guides the outer catheter through a transoral approach and includes a passage for the outer catheter. Even if an endoscope could permit vascular access, which it cannot, their would be no reason to add an additional layer to the device of Gambale.

With respect to the dependent claims 47 through 49, Gambale also fails to teach or disclose a self-expanding stent adapted to drain a gastric pseudocyst when

implanted. Moreover, the implants of Gambale do not correspond to a self-expanding stent adapted to drain a gastric pseudocyst when implanted and having a diameter when expanded that is larger than the diameter of an individual endobiliary tube. The disclosure of Gambale also does not teach or suggest a self-expanding gastric stent that has an expanded diameter of greater than about 8 mm.

The implants of Gambale are not configured for delivery via a trans-oral approach or for implantation into a gastric or abdominal wall for treating a pseudocyst. Instead, Gambale's implants are implanted in cardiac tissue, particularly the myocardium of the heart. Instead of permitting drainage, Gambale's implants intentionally cause tissue injury to promote vascularization and blood vessel growth. Moreover, Gambale states that the implants should have a small profile; 1.0 to 1.5 mm to facilitate tissue penetration. Col. 8, line 51-53. Once positioned, the implants expand to a size of 2.0 to 2.5 mm to cause tissue irritation and injury. Col. 8, ll. 59-64. Such implants differ substantially from the pseudocyst draining stent required by claims 47, 48, and 49.

One skilled in the art, after reviewing the disclosure of Gambale, would have no reason to reconfigure the implants of Gambale to meet the limitations of claims 47 through 49. In particular, one skilled in the art would have no reason to change the dimensions of Gambale's implants because Gambale's implants are specifically configured for cardiac applications. Using an implant larger than that disclosed by Gambale could possibly cause unwanted tissue damage in a sensitive and vital organ; the heart. Moreover, Gambale's focus on *small* implants to produce *minimal injury* teaches away from scaling the implants to a size that could permit pseudocyst drainage.

Instead, the implants described in Gambale are sized much closer to conventional endobiliary tubes.

One skilled in the art would not consider Gambale relevant when looking for solutions to treating a gastric pseudocyst. Gambale's implants are particularly suited for cardiac applications and causing blood vessel growth. Even if considered relevant, Gambale teaches away from increasing the size of the implants because Gambale's implants are adapted for a particular use, namely angiogenesis. Larger implants would be at odds with the purpose (angiogenesis) and intended use (cardiac) of the Gambale reference. Moreover, one skilled in the art would have no reason, aside from hindsight, to choose a larger device for draining pseudocysts because conventional treatments use much smaller devices. If anything, one skilled in the art would select implants having the same size as Gambale because the implants of Gambale correspond in size to conventional endobiliary tubes.

The Gambale reference fails to teach or disclose the system of claim 24. In particular, Gambale lacks an endoscope for transoral delivery of the claimed stent. Moreover, with respect to dependent claim 47, Gambale lacks a self-expanding stent adapted to drain a gastric pseudocyst when implanted. In addition, the disclosure of Gambale is at odds with a gastric stent having a diameter when expanded that is larger than the diameter of an individual endobiliary tube or greater than about 8 mm. Accordingly, Applicants respectfully submit that the rejection of independent claim 24, and the claims dependent thereon, should be withdrawn.

B. The Phelps Reference

The Examiner rejects claims 24, 25, 29-31, and 33 pursuant to 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,290,728 to Phelps et al. ("Phelps"). In particular, with respect to independent claim 24, the Office Action states that:

> Phelps discloses a stent delivery system comprising: an inner catheter (22) with a first lumen; perforating means (16) slidably disposed in the first lumen; an outer catheter (26) adapted for axial movement relative to the inner catheter; a self expandable stent (20) disposed between the inner and outer catheter.

Office Action at p. 3.

Applicants respectfully traverse this rejection because Phelps fails to suggest or disclose an endoscope wherein the outer catheter is sized for receipt within the endoscope and the endoscope is configured for intraoral introduction and a self-expanding stent adapted to drain a gastric pseudocyst when implanted. In addition, Phelps lacks an outer catheter extending over a majority of the length of an inner catheter as required by new dependent claim 50.

The Phelps reference is directed to a method for creating a conduit in the myocardium or heart wall to permit passage of blood flow between the left ventricle and the coronary artery. In one aspect, the conduit is provided by a cardiac stent that is implanted in cardiac tissue. Phelps does not mention gastric applications or the treatment of gastric pseudocysts.

Conversely, claim 24 of the present '570 Application recites an inner catheter having a first longitudinally extending lumen, perforating means slidably disposed in said first longitudinally extending lumen, and an outer catheter surrounding at least a portion of the length of the inner catheter and adapted for axial movement relative to the inner catheter and a self-expandable stent disposed between the inner catheter and

said outer catheter. In addition, claim 24 requires an endoscope for housing the inner and outer catheter and stent.

Given the cardiac focus of Phelps and the accompanying desire to minimize the size of a delivery device, one of ordinary skill in the art would have no reason to provide an endoscope in association with the device of Phelps. An endoscope is not an appropriate tool for delivering *cardiac* stents and could not be driven though Phelps' desired access path, blood vessels.

In addition, the delivery device of Phelps is self sufficient and the addition of unnecessary structures to the device of Phelps would be at odds with Phelps' disclosure. Thus, even if the Examiner were to point to the mere mention in Phelps of non-cardiac applications, there is no suggestion that an endoscope should be used for those non-cardiac applications. Instead, where Phelps says "[i]t should be appreciated that the stents described above, and particularly the bulkhead stent, are useful in other applications in addition to stenting the myocardium," one skilled in the art would be, at best, motivated to use the disclosed stents and delivery devices of Phelps for those non-cardiac applications.[1,2]

One skilled in the art, after reviewing the disclosure of Phelps, would have no reason to reconfigure the cardiac stent of Phelps and the delivery device of Phelps to permit drainage of a pseudocyst. In particular, one skilled in the art would have no reason to use an endocope to deliver the delivery device of Phelps.

The Phelps reference thus fails to teach or disclose the system of claim 24. In addition, with respect to new claim 50, Phelps lacks an outer catheter extending over a

[1] col. 9, ll. 17-19.

majority of the length of the inner catheter. In fact, instead of an outer catheter Phelps uses a "sheath" to restrain a cardiac stent. One skilled in the art would have had no reason to extend the sheath of Phelps to cover a majority of the length of the device of Phelps.

Accordingly, Applicants respectfully submit that the rejection of independent claim 24, and the claims dependent thereon, should be withdrawn.

§103(a) Rejections

The Examiner rejects claims 24, 25, 27, 30, 33, and 34 pursuant to 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 6,599,315 to Wilson in view of U.S. Patent No. 6,533,753 to Haarstad et al. ("Haarstad"), and further in view of Phelps. In particular the Office Action states that:

> Wilson discloses a stent delivery system comprising: an inner catheter (120) with a first lumen (125) with a guide wire (150) slidable disposed in the first lumen; a second lumen (126) with a guidewire (151) slidably disposed in the second lumen; and a self expandable stent (20) (Col 6, line 62) coaxially disposed over the inner catheter.
> ...
> Wilson in view of Haarstad does not disclose an outer catheter.
>
> Phelps discloses that it is well know to use a sheath (outer catheter) to restrain a self-expanding stent to hold the stent in a non-expanded configuration.

Office Action at pp. 4-5.

Wilson is directed to a stent delivery catheter for delivering and implanting a stent at or near an area of septal perforations. The delivered stents have openings that correspond to septal perforations to prevent covering of the orifices of the septal

[2] In addition, this cited passage refers particularly to other uses for "bulkhead stents." Conversely, the claimed system requires self-expandable stents.

perforation when the stent is expanded. The delivery catheter includes an opening (145) in the side wall that is aligned with an opening or openings in the stent. In use, a guide wire (151) is moved from within the catheter, through the opening (145) in the catheter, through the opening in the stent, and into a septal perforation (7). Placement of the guide wire (151) in the septal opening (7) permits alignment of the opening in the stent (20) with the septal perforation (7). FIG. 18 of Wilson, reproduced below, illustrates this concept.

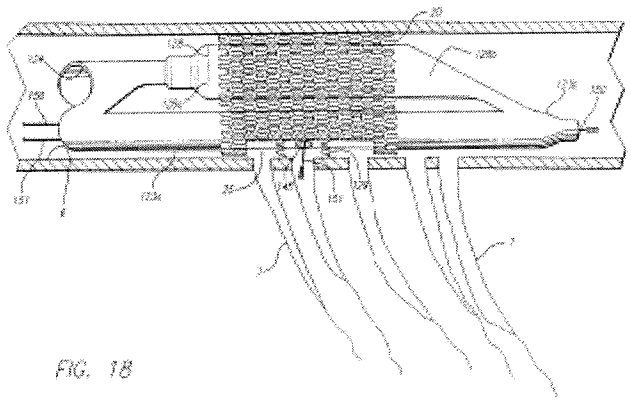

FIG. 18

Because Wilson uses an opening in the sidewall of the catheter to pass a guide wire into a septal perforation, use of an outer catheter would destroy the utility of Wilson's system. Placing an outer catheter around the catheter of Wilson would prevent Wilson's guide wire from entering a septal perforation. The guide wire permits alignment of Wilson's stent with the septal perforations, and appears critical to the operation of Wilson's system. Thus, the use of an outer catheter is at odds with Wilson's stent delivery system and it would be inappropriate to add an outer catheter to the Wilson system based on the disclosure of Phelps.

The Haarstad reference was cited to teach that "it is well known in the art to use a stiff guidewire to penetrate lesions," a concept not found in the Wilson reference. However, the Haarstad reference does not remedy the deficiencies of the Wilson or Phelps references as discussed above. In particular, Haarstad does not suggest or disclose an outer catheter that could be added to Wilson's stent delivery system. Accordingly, the rejection of claims 24, 25, 27, 30, 33, and 34 over Wilson in view of Haarstad and Phelps cannot stand.

Conclusion

In consideration of the forgoing remarks, Applicants respectfully requests reconsideration of this application and allowance of the pending claims. Should any issue remain outstanding, please feel free to contact the undersigned.

If there is any fee due in connection with the filing of this Amendment, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: March 12, 2008

By: 
Kevin Cronin
Reg. No. 47,203